

REMARKS

This communication is submitted in response to the Office Action of July 18, 2005.

Claims 1-26 are pending in the subject application with claims 1 and 3-9 being amended herewith and claims 27-32 being canceled herewith. Claims 2 and 10-26 have not been changed relative to their immediate prior version. Claims 10-26 stand allowed by the Examiner.

The specification has been amended to correct various typographical errors, and the amendments to the specification do not introduce any new matter.

Support for the amended claims is found throughout the specification as originally filed, and the amended claims do not introduce any new matter.

Reconsideration of the subject application is respectfully requested in view of the foregoing amendments and the following remarks.

Claim 4 stands objected to by the Examiner as being dependent upon a rejected base claim, but was indicated as being allowable if rewritten in independent form to include all of the limitations of the base claim and any intervening claims. Since claim 4 has been amended to be rewritten in independent form to include all of the limitations of its base claim and intervening claims, independent claim 4 should now be allowable.

The rejection of claims 1-3 and 5 as being anticipated by Rosier and the rejection of claims 1 and 6-9 as being anticipated by Spitz et al are respectfully traversed for the following reasons.

Initially, it is pointed out that independent claim 1 has been amended for consistency with its dependent claims and for greater clarity of language without narrowing the scope of the claims in response to the Examiner's rejection based on

prior art. Similarly, dependent claims 3 and 5-9 have been amended for greater clarity and for consistency with independent claim 1 without narrowing the scope of the claims.

Independent claim 1 requires the steps of contacting anatomical tissue with the stimulus probe in an area of the nerve structure; detecting a change in impedance of the stimulus probe resulting from contact of the stimulus probe with the anatomical tissue; and triggering a sequence of pre-programmed intraoperative neurophysiological monitoring algorithm steps in response to the detection of the change in impedance of the stimulus probe. Rosier does not teach or suggest the steps of detecting and triggering recited in claim 1.

Rosier discloses the application of an electrical stimulus to a nerve via a pair of stimulus electrodes 10 connected to a nerve stimulator 12, which supplies an electrical impulse to the stimulus electrodes 10. Rosier discloses that the stimulus electrodes 10 are held over the nerve at the desired point of stimulus (col. 3, line 42-43) and, when a stimulus is supplied to the electrodes 10 by the nerve stimulator 12, it causes a nerve discharge or muscle action potential to travel along the nerve until it reaches a muscle that is enervated by the nerve and causes the muscle to contract (col. 3, lines 3-7 and 57-60). The muscle action potential is detected by a pair of pick-up electrodes 24 placed over the muscle. The pick-up electrodes 24 are connected to a preamplifier 26. When the muscle contracts, the preamplifier 26 detects the muscle action potential as a potential difference between the two pick-up electrodes 24 (col. 3, lines 7-9). A signal derived from the potential difference is supplied to a comparator 30 and is used to calculate the elapsed time between the stimulus and the muscle contractions (col. 3, lines 7-11 and 16-19), which may be used in combination with the distance from the

stimulus electrodes 10 to the pick-up electrodes 24 to determine the nerve conduction velocity (col. 3, lines 19-24).

Rosier does not involve the detection of a change in impedance of the stimulus electrodes 10 resulting from contact of the stimulus electrodes 10 with anatomical tissue. The passages of Rosier referred to by the Examiner do not teach or suggest the step of detecting recited in claim 1. Rather, the passages of Rosier referred to by the Examiner relate primarily to detection carried out at the pick-up electrodes 24 and not to any detection at the stimulus electrodes 10, much less detection of a change in impedance of the stimulus electrodes resulting from contact of the stimulus electrodes with anatomical tissue. No disclosure whatsoever is provided by Rosier either explicitly or inferentially of detecting a change in impedance of the stimulus electrodes 10, and it follows that Rosier does not disclose or suggest the step of triggering as recited in claim 1 which occurs in response to the detection of a change in impedance of the stimulus probe. Accordingly, it is submitted that independent claim 1 cannot be anticipated by Rosier and that claim 1 is clearly patentable over Rosier along with its dependent claims 2, 3 and 5-9.

Dependent claim 2 recites the step of triggering as comprising closing a circuit between a current source and the stimulus probe to provide stimulus current to the nerve structure. Rosier discloses that the stimulator 12 is actuated by a switch 13 to provide the stimulus to the electrodes 10. However, there are no teachings or suggestions whatsoever by Rosier that actuation of the switch 13 is triggered in response to the detection of a change in impedance of the electrodes 10. It is submitted, therefore, that claim 2 cannot be anticipated by Rosier and that claim 2 is

clearly patentable over Rosier for the additional limitations recited therein as well as being allowable with independent claim 1.

Dependent claim 3 recites the step of triggering as comprising generating a visible or audible indication of appropriate impedance of the stimulus probe resulting from contact of the stimulus probe with the anatomical tissue. The Examiner asserts that Rosier discloses the step of generating, without identifying any support in Rosier to show where the step of generating is disclosed. Indeed, there being no detection by Rosier of a change in impedance of the stimulus probe, it follows that the step of generating a visible or audible indication of appropriate impedance of a stimulus probe can not be disclosed or suggested by Rosier. Accordingly, dependent claim 3 is submitted to be clearly patentable over Rosier for the additional limitations recited therein as well as being allowable with independent claim 1.

Dependent claim 5 recites the step of triggering as comprising initiating generation of a pre-programmed sequence of stimulus pulses to be supplied to the nerve structure via the stimulus probe and storing measured responses to the stimulus pulses collected from an electrode connected to the enervated muscle. In Rosier, the stimulus provided to stimulus electrodes 10 from the nerve stimulator 12 is not initiated in response to the detection of a change in impedance of the stimulus electrodes 10 but, rather, is initiated merely by actuating a switch 13 on the nerve stimulator 12. Furthermore, no teachings or suggestions are provided by Rosier of storing measured responses to the stimulus collected from the pick-up electrodes 24, and Rosier does not disclose any component which would make the step of storing inherent to his digital electroneurometer. It is submitted, therefore, that dependent claim 5 is clearly

patentable over Rosier for the additional limitations recited therein as well as being allowable with independent claim 1.

The steps recited in claim 1 are not disclosed or suggested by Spitz et al. Like Rosier, the system disclosed by Spitz et al is based on monitoring nerve conduction velocity. The nerve condition monitoring system of Spitz et al includes stimulating electrodes 44 disposed in contact with a patient's forearm and pick-up electrodes 40 in contact with the patient's finger. A stimulating signal generator is coupled to the stimulating electrodes 40 for generating electrical stimulating signals, and a response signal processor is coupled to the pick-up electrodes for processing neurological response signals received at the pick-up electrodes. Spitz et al discloses a self-checking operation involving the determination of the quality of patient-electrode contact by monitoring the signal level generated at the pick-up electrodes 40 in the absence of a stimulating signal (col. 13, lines 19-24).

Operation of the monitoring system disclosed by Spitz et al does not involve detecting a change in impedance of the stimulating electrodes 44 resulting from contact of the stimulating electrodes with the anatomical tissue of the patient. The self-checking operation disclosed by Spitz et al for determining the quality of patient-electrode contact is based on monitoring the signal level generated at the pick-up electrodes 40 and is unrelated to detecting a change in impedance of the stimulating electrodes 44. None of the other operations performed by the monitoring system of Spitz et al involve detecting a change in impedance of the stimulating electrodes 44, much less detecting a change in impedance of the stimulating electrodes resulting from contact of the stimulating electrodes with the anatomical tissue. There being no step of detecting a change in

impedance of the stimulating electrodes 44 in Spitz et al, it follows that Spitz et al does not and cannot teach or suggest the step of triggering a sequence of pre-programmed intraoperative neurophysiological monitoring algorithm steps in response to the detection of the change in impedance of the stimulus probe. None of the passages of Spitz et al referred to by the Examiner can fairly be interpreted as providing a disclosure of either the step of detecting or triggering recited in claim 1, both of which are based on detecting a change in impedance of the stimulus probe. Accordingly, it is submitted that independent claim 1 cannot be anticipated by Spitz et al and that claim 1 is clearly patentable over Spitz et al and should be allowed along with its dependent claims 2, 3 and 5-9.

Each of dependent claims 6-9 stands rejected as being anticipated by Spitz et al, and each of dependent claims 6-9 depend from claim 5 which recites the step of triggering as comprising initiating generation of a pre-programmed sequence of stimulus pulses to be supplied to the nerve structure via the stimulus probe. As discussed above, Spitz et al does not teach or suggest a step of triggering that is responsive to the detection of a change in impedance of the stimulating electrodes 44, there being no detection of a change in impedance of the stimulating electrodes 44 in Spitz et al. For this reason, none of dependent claims 5-9 can properly be anticipated by Spitz et al and, in addition, each of claims 5-9 are submitted to be clearly patentable over Spitz et al for the additional limitations recited therein.

In light of the foregoing, all of the claims in the subject application are submitted to be in condition for allowance. Action in conformance therewith is courteously solicited. Should any issues in the subject application remain unresolved, the Examiner

is encouraged to contact the undersigned attorney.

Respectfully submitted,



Robert H. Epstein
Registration No. 24,353

EPSTEIN & GERKEN
1901 Research Boulevard, Suite 340
Rockville, Maryland 20850
(301) 610-7634

I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: MAIL STOP: PATENT APPLICATION, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450 on October 17, 2005.

Ann L. Shebovsky